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Manual

IDK® Calprotectin ELISA

For the in vitro determination of calprotectin (MRP 8/14, S100A8/A9) in stool

Valid from 2024-08-01

REF **K 6927**

REF **K 6927.20**

Σ 96

Σ 20 x 96

+8 °C
+2 °C

IVD

CE

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1. INTENDED USE

This Immundiagnostik AG assay is an enzyme immunoassay intended for the quantitative determination of calprotectin (MRP (8/14, S100A8/A9) in stool. For *in vitro* diagnostic use only.

2. INTRODUCTION

Alternative names:

- Calgranulin A: MRP8, S100A8, CP-10 (in mouse)
- Calgranulin B: MRP14, S100A9,
- MRP8/14: L1, (p8,14), p34

Calprotectin is a calcium-binding protein secreted predominantly by neutrophils and monocytes. Faecal calprotectin is a marker for neoplastic and inflammatory gastrointestinal diseases.

It is often difficult to distinguish between irritable bowel syndrome and chronic inflammatory bowel disease. This leads in many cases to extensive and unnecessary colonoscopic examinations. The calprotectin test allows clear differentiation between the two patient groups. Faecal calprotectin levels correlate significantly with histologic and endoscopic assessment of disease activity in Crohn's disease and ulcerative colitis as well as with the faecal excretion of indium-111-labelled neutrophilic granulocytes that has been suggested as the "gold standard" of disease activity in inflammatory bowel disease. However, measuring 111-indium-labelled granulocytes is very costly (patient's hospitalisation, analysis and disposal of isotopic material) and is connected with radioactive exposition of the patients. For this reason, a repeated application to children and pregnant women is not recommended.

Elevated levels of calprotectin are a much better predictor of relapse than standard inflammatory markers (CRP, ESR HB). Comparing this marker with standard faecal occult blood screening in colorectal cancer demonstrates clearly the diagnostic advantages of the faecal calprotectin test. The parameter is of a high diagnostic value: if the calprotectin level in stool is low, the probability is high that no organic intestinal disease exists.

Indications

- Marker for acute inflammation
- Estimation of gastrointestinal inflammation degree
- Parameter for monitoring Crohn's disease, Colitis ulcerosa or the patient's status after removal of polyps.
- Discrimination between patients with inflammatory bowel disease (acute Crohn's disease and ulcerative colitis) and irritable bowel syndrome when a faecal test system

3. MATERIAL SUPPLIED

Cat. No.	Label	Kit components	Quantity for cat. no.	
			K 6927	K 6927.20
K 6927	PLATE	Microtiter plate, pre-coated	12 x 8 wells	20 x 12 x 8 wells
K 0001.C.100	WASHBUF	Wash buffer concentrate, 10x	2 x 100 ml	40 x 100 ml
K 6927	CONJ	Conjugate, ready-to-use, peroxidase-labelled	1 x 15 ml	20 x 15 ml
K 6927	STD	Standards, ready-to-use (0; 13; 52; 210; 840 ng/ml)	1 x 5 vials	20 x 5 vials
K 6927	CTRL1	Control, ready-to-use (see specification for range)	1 x 1 vial	20 x 1 vial
K 6927	CTRL2	Control, ready-to-use (see specification for range)	1 x 1 vial	20 x 1 vial
K 6927	SAMPLEBUF	Sample dilution buffer, ready-to-use	1 x 100 ml	10 x 100 ml
K 0002.15	SUB	Substrate (tetramethyl-benzidine), ready-to-use	1 x 15 ml	20 x 15 ml
K 0003.15	STOP	Stop solution, ready-to-use	1 x 15 ml	20 x 15 ml
K 6999.C.100	IDK Extract®	Extraction buffer concentrate *IDK Extract*® 2.5x	1 x 100 ml	–

For reorders of single components, use the catalogue number followed by the label as product number.

4. MATERIAL REQUIRED BUT NOT SUPPLIED

- Ultrapure water*
- Calibrated precision pipettors and 10–1 000 µl single-use tips
- Foil to cover the microtiter plate
- Multi-channel pipets or repeater pipets
- Vortex
- Standard single-use laboratory glass or plastic vials, cups, etc.
- Microtiter plate reader (required filters see chapter 7)

* Immundiagnostik AG recommends the use of ultrapure water (water type 1; ISO 3696), which is free of undissolved and colloidal ions and organic molecules (free of particles > 0.2 µm) with an electrical conductivity of 0.055 µS/cm at 25 °C (≥ 18.2 MΩ cm).

5. STORAGE AND PREPARATION OF REAGENTS

- To run assay more than once, ensure that reagents are stored at conditions stated on the label. **Prepare only the appropriate amount necessary for each run.** The kit can be used up to 4 times within the expiry date stated on the label.
- **Preparation of the wash buffer:** The **wash buffer concentrate (WASH-BUF)** has to be diluted with ultrapure water **1:10** before use (100 ml WASH-BUF + 900 ml ultrapure water), mix well. Crystals could occur due to high salt concentration in the concentrate. Before dilution, the crystals have to be redissolved at room temperature or in a water bath at 37 °C. The **WASHBUF** is stable at **2–8 °C** until the expiry date stated on the label. **Wash buffer** (1:10 diluted WASHBUF) can be stored in a closed flask at **2–8 °C for 1 month**.
- **Preparation of the extraction buffer:** The **extraction buffer concentrate *IDK Extract*®** has to be diluted with ultrapure water **1:2.5** before use (100 ml *IDK Extract*® + 150 ml ultrapure water), mix well. Crystals could occur due to high salt concentration in the concentrate. Before dilution, the crystals have to be redissolved at 37 °C in a water bath. The ***IDK Extract*®** is stable at **2–8 °C** until the expiry date stated on the label. Extraction buffer (1:2.5 diluted *IDK Extract*®) can be stored in a closed flask at **2–8 °C for 4 months**.
- All other test reagents are ready-to-use. Test reagents are stable until the expiry date (see label) when stored at **2–8 °C**.

6. STORAGE AND PREPARATION OF SAMPLES

Stability and storage of samples

Raw stool

Calprotectin in stool is described to be stable for at least 3 days at room temperature (Tøn et al. (2000) Clin Chim Acta). Nevertheless, we recommend storing the samples for no more than 48 h at 2–8 °C and transporting the samples at room temperature for maximum 2 days. Long term storage up to 12 months is recommended at -20 °C. Allow frozen samples to thaw slowly, preferably at 2–8 °C, and warm the samples to room temperature before analysis. Avoid repeated freezing and thawing of the sample. Freezing can cause neutrophil granulozytes in the stool sample to burst and release calprotectin. Therefore frozen samples can be expected to contain slightly elevated concentrations of calprotectin compared to fresh samples.

Chemical or biological additives in stool sample tubes may interfere with *IDK*® Calprotectin. Therefore use only empty tubes or tubes filled with the extraction buffer *IDK Extract*® supplied by Immundiagnostik AG.

Stool extracts

Stool extract is stable for nine days at room temperature, 2–8 °C or -20 °C. Avoid more than three freeze-thaw cycles.

Extraction of the stool samples

Extraction buffer (1:2.5 diluted *IDK Extract*®) is used as a sample extraction buffer. We recommend the following sample preparation:

Stool Sample Application System (SAS) (Cat. No.: K 6998SAS)

Stool sample tube – Instructions for use

Please note that the dilution factor of the final stool suspension depends on the amount of stool sample used and the volume of the buffer.

SAS with 1.5 ml sample extraction buffer:

Applied amount of stool:	15 mg
Buffer Volume:	1.5 ml
Dilution Factor:	1:100

Please follow the instructions for the preparation of stool samples using the SAS as follows:

a) The raw stool sample has to be thawed. For particularly heterogeneous samples we recommend a mechanical homogenisation using an applicator, inoculation loop or similar device.

b) Fill the **empty stool sample tube** with **1.5 ml extraction buffer** (1:2.5 diluted *IDK Extract*®) before using it with the sample. **Important:** Allow the sample extraction buffer to reach room temperature.

c) Unscrew the tube (yellow part of cap) to open. Insert the yellow dipstick into the sample. The lower part of the dipstick has notches which need to be covered completely with stool after inserting it into the sample. Place dipstick back into the tube. When putting the stick back into the tube, excess material will be stripped off, leaving 15 mg of sample to be diluted. Screw tightly to close the tube.

d) Vortex the tube well until no stool sample remains in the notches. **Important:** Please make sure that you have a maximally homogenous suspension after shaking. Especially with more solid samples, soaking the sample in the tube with sample extraction buffer for ~ 10 minutes improves the result.

e) Allow the sample to stand for ~10 minutes until sediment has settled. Floating material like shells of grains can be neglected.

f) Carefully unscrew the complete cap of the tube including the blue ring plus the dipstick. Discard cap and dipstick. Make sure that the sediment will not be dispersed again.

Dilution I: 1:100

Dilution of samples

The supernatant of the sample preparation procedure (dilution I) is diluted **1:25 in sample dilution buffer (SAMPLEBUF)**. For example:

40 µl supernatant (dilution I) + **960 µl** sample dilution buffer, mix well = **1:25** (**dilution II**). This results in a final dilution of 1:2 500.

100 µl of **dilution II** are used in the test.

7. ASSAY PROCEDURE

Principle of the test

This ELISA is designed for the quantitative determination of calprotectin.

The assay utilises the two-site sandwich technique with two selected monoclonal antibodies that bind to human calprotectin.

Standards, controls and diluted patient samples which are assayed for human calprotectin are added to wells of microplate coated with a high affine monoclonal anti-human calprotectin antibody. During the first incubation step, calprotectin in the samples is bound by the immobilised antibody. Then a peroxidase labelled conjugate is added to each well and the following complex is formed: capture antibody – human calprotectin – peroxidase conjugate. Tetramethylbenzidine (TMB) is used as a substrate for peroxidase. Finally, an acidic stop solution is added to terminate the reaction. The colour changes from blue to yellow. The intensity of the yellow colour is directly proportional to the calprotectin concentration of sample. A dose response curve of the absorbance unit (optical density, OD at 450 nm) vs. concentration is generated, using the values obtained from the standard. Calprotectin, present in the patient samples, is determined directly from this curve.

Test procedure

Bring all **reagents and samples to room temperature** (15–30 °C) and mix well.

Mark the positions of standards/controls/samples on a protocol sheet.

Take as many microtiter strips as needed from kit. Store unused strips together with the desiccant bag in the closed aluminium packaging at 2–8 ° C. Strips are stable until expiry date stated on the label.

For automated ELISA processors, the given protocol may need to be adjusted according to the specific features of the respective automated platform. For further details please contact your supplier or Immundiagnostik AG.

We recommend to carry out the tests in duplicate.

1.	Add each **100 µl standards/controls/diluted samples** into the respective wells.
2.	Cover the strips and incubate for **30 min at room temperature** (15–30 °C).
3.	Discard the content of each well and wash **5 times** with **250 µl wash buffer**. After the final washing step, remove residual wash buffer by firmly tapping the plate on absorbent paper.

4.	Add **100 µl conjugate** (CONJ) into each well.
5.	Cover the strips and incubate for **30 min at room temperature** (15–30 °C).
6.	Discard the content of each well and wash **5 times** with **250 µl wash buffer**. After the final washing step, remove residual wash buffer by firmly tapping the plate on absorbent paper.
7.	Add **100 µl substrate** (SUB) into each well.
8.	Incubate for **10–20 min*** at room temperature (15–30 °C) in the **dark**.
9.	Add **100 µl stop solution** (STOP) into each well and mix well.
10.	Determine **absorption immediately** with an ELISA reader at **450 nm** against 620 nm (or 690 nm) as a reference. If no reference wavelength is available, read only at 450 nm. If the extinction of the highest standard exceeds the range of the photometer, absorption must be measured immediately at **405 nm** against 620 nm as a reference.

* The intensity of the colour change is temperature sensitive. We recommend observing the colour change and stopping the reaction upon good differentiation.

8. RESULTS

The following algorithms can be used alternatively to calculate the results. We recommend using the "4 parameter algorithm".

1. 4 parameter algorithm

It is recommended to use a linear ordinate for the optical density and a logarithmic abscissa for the concentration. When using a logarithmic abscissa, the zero standard must be specified with a value less than 1 (e. g. 0.001).

2. Point-to-point calculation

We recommend a linear ordinate for the optical density and a linear abscissa for the concentration.

3. Spline algorithm

We recommend a linear ordinate for the optical density and a linear abscissa for the concentration.

The plausibility of the duplicate values should be examined before the automatic evaluation of the results. If this option is not available with the programme used, the duplicate values should be evaluated manually.

Stool samples

The obtained results have to be multplied by the **dilution factor** of **2 500** (dilution I × dilution II) to get the actual concentrations.

In case **another dilution factor** has been used, multiply the obtained result by the dilution factor used.

9. LIMITATIONS

Samples with concentrations above the measurement range (see definition below) can be further diluted and re-assayed. Please consider this higher dilution when calculating the results.

Samples with concentrations lower than the measurement range (see definition below) cannot be clearly quantified.

The upper limit of the measurement range can be calculated as:

highest concentration of the standard curve × sample dilution factor to be used

The lower limit of the measurement range can be calculated as:

LoB × sample dilution factor to be used

LoB see chapter "Performance Characteristics".

10. QUALITY CONTROL

Immundiagnostik AG recommends the use of external controls for internal quality control, if possible.

Control samples should be analysed with each run. Results, generated from the analysis of control samples, should be evaluated for acceptability using appropriate statistical methods. The results for the patient samples may not be valid if within the same assay one or more values of the quality control sample are outside the acceptable limits.

Reference range

1 g stool is equivalent to 1 ml.

- The median value in healthy adults is about 25 µg/g (mg/kg)[5].
- Samples with a calprotectin concentration < 50 µg/g are regarded as negative.
- Samples with a calprotectin concentration between 50 µg/g and 100 µg/g are regarded as borderline positive. We recommend repeating the measurement at a later time point in order to confirm the result.
- Samples with a calprotectin concentration > 100 µg/g are regarded as positive.

We recommend each laboratory to establish its own reference concentration range.

Note: Many confounding factors can cause increased levels of faecal calprotectin in the absence of IBD or IBD in a quiescent disease phase, e. g. use of NSAIDs (non steroidal anti inflammatory drugs), any intercurrent gastrointestinal infection, and the presence of malignancies. These factors should be considered in the interpretation of the test results and therapy of IBD[1,10].

Reference ranges for faecal calprotectin in children

Hestvik E et al. (2011) *BMC Pediatrics* **11**:9 doi:10.1186/1471-2431-11-9

Method: 302 appararently healthy children, age 0–12 years, in Kampala, Uganda, were tested for faecal Calprotectin concentration.

Table 1: Table 1: Faecal calprotectin concentration in apparently healthy children by age. 95% confidence interval (95% CI) is indicated in brackets.

Age	Number (%)	Median calprotectin [µg/g] (95% CI)
0–3 months	14 (4.6)	345 (195–621)
3–6 months	13 (4.3)	278 (85–988)
6–12 months	27 (8.9)	183 (109–418)
1–4 years	89 (29.5)	75 (53–119)
4–12 years	159 (52.6)	28 (25–35)

Conclusion: Concentrations of faecal calprotectin among apparently healthy children in Uganda are comparable to those in healthy children living in high-income countries. In healthy infants faecal calprotectin is high; in children older than 4 years faecal calprotectin concentration is low.

Fagerberg UL et al. (2003) *J Pediatr Gastroenterol Nutr* **37**:468-472

Method: 117 healthy children age 4–17 years were tested for faecal calprotectin concentration.

Table 2: Faecal calprotectin concentration in healthy children by age.

Age	Number	Median faecal calprotectin [µg/g]
4–6 years	27	28.2
7–10 years	30	13.5
11–14 years	27	9.9
15–17 years	33	14.6

Conclusion: The suggested cut-off level for adults (< 50 µg/g) can be used for children aged 4–17 years.

11. PERFORMANCE CHARACTERISTICS

The following values have been estimated based on the concentrations of the standard curve without considering possibly used sample dilution factors.

Analytical specificity

The specificity of the antibody was tested by measuring the cross-reactivity against against a range of compounds with structural similarity to calprotectin. There was no cross-reactivity observed.

Substance tested	Concentration added [ng/ml]	Concentration obtained [ng/ml]	Conclusion
Lysozyme	10 000	< 0.957	< LoB
PMN Elastase	1 000	2.003	0.2 %
MPO	10 000	< 0.957	< LoB
Laktoferrin	100 000	< 0.957	< LoB

Analytical specificity – Interferences

Different substances that might interfere when using the *IDK*® Calprotectin ELISA were tested. Therefore, high level as well as low level stool extracts were supplemented with drugs (maximum daily dose) and then measured.

No interferences with the following drugs were found: Azathioprin, Pantoprazol, Mesalazin, Clariothromycin, Levofloxacin, iron supplements, acetylsalicylic acid, Vitamin D, Gabapentin, Multivitamin preparation or Ibuprofen.

Linearity

The linearity states the ability of a method to provide results proportional to the concentration of analyte in the test sample within a given range. This was assessed according to CLSI guideline EP6-A by means of a ratio dilution of 4 different stool samples.

For calprotectin in stool, the method has been demonstrated to be linear from 15.1 to 1 726.8 µg/ml, showing a non-linear behaviour of less than ± 15 % in this interval.

Sample	Dilution	Expected [µg/ml]	Obtained [µg/ml]	Recovery [%]
A	50 %	864.2	715.4	82.8
	60 %	1036.7	880.6	84.9
	70 %	1209.3	1091.4	90.3
	80 %	1381.8	1264.2	91.5
	90 %	1554.3	1524.6	98.1
	100 %	1726.8	1726.8	100.0
B	10 %	80.7	85.5	106.0
	20 %	154.3	149.7	97.0
	30 %	227.9	245.7	107.8
	40 %	301.5	305.6	101.3
	50 %	375.1	365.2	97.4
	60 %	448.8	440.7	98.2
	70 %	522.4	507.5	97.1
	80 %	596.04	571.5	95.9
	90 %	669.6	664.2	99.2
	100 %	743.2	743.2	100.0

Sample	Dilution	Expected [µg/ml]	Obtained [µg/ml]	Recovery [%]
C	10 %	28.9	32.5	112.4
	20 %	49.2	58.3	118.4
	30 %	69.6	75.0	107.8
	40 %	89.9	103.2	114.8
	50 %	110.2	125.9	114.3
	60 %	130.6	147.2	112.8
	70 %	150.9	176.4	116.9
	80 %	171.2	185.9	108.6
	90 %	191.5	211.9	110.6
	100 %	211.9	211.9	100.0
D	10 %	15.1	14.9	99.0
	20 %	22.4	21.1	94.1
	30 %	29.7	33.61	113.2
	40 %	37.1	38.7	104.3
	50 %	44.4	45.3	102.0
	60 %	51.7	52.0	100.5
	70 %	59.0	57.7	97.7
	80 %	66.4	64.8	97.6
	90 %	73.7	77.5	105.2
	100 %	81.0	81.0	100.0

Accuracy – Precision

Repeatability (Intra-Assay); n = 20

The repeatability was assessed with 2 stool samples under **constant** parameters (same operator, instrument, day and kit lot).

Sample	Mean value [µg/g]	CV [%]
1	89.19	5.6
2	229.05	3.2

Reproducibility (Inter-Assay); n = 25

The reproducibility was assessed with 3 stool samples under **varying** parameters (different operators, instruments, days and kit lots).

Sample	Mean value [µg/g]	CV [%]
1	59.17	11.60
2	253.34	8.82
3	490.31	9.11

Analytical sensitivity

Limit of blank, LoB	0.957 ng/ml
Limit of detection, LoD	2.267 ng/ml
Limit of quantitation, LoQ	4.767 ng/ml

The evaluation was performed according to the CLSI guideline EP17-A2. The specified accuracy goal for the LoQ was 15 % CV.

Traceability

The standards of the *IDK*® Calprotectin ELISA are based on recombinant human calprotectin which has been calibrated against purified MRP8/14 derived from human granulocytes.

Accuracy – Trueness

The trueness states the closeness of the agreement between the result of a measurement and the true value of the measurand. Therefore, calprotectin spikes with known concentrations were added to 2 different stool samples.

Sample [ng/ml]	Spike [ng/ml]	Expected [ng/ml]	Obtained [ng/ml]	Recovery [%]
21.02	173.21	194.23	213.00	109.66
	63.28	84.30	90.76	107.66
	40.48	61.50	62.66	101.90
	17.47	38.49	41.00	106.52
	10.46	31.48	33.28	105.71

Sample [ng/ml]	Spike [ng/ml]	Expected [ng/ml]	Obtained [ng/ml]	Recovery [%]
18.23	173.21	191.44	188.73	98.58
	63.28	81.52	83.17	102.02
	40.48	58.71	59.34	101.08
	17.47	35.71	35.60	99.71
	10.46	28.69	29.60	103.16

12. PRECAUTIONS

- All reagents in the kit package are for *in vitro* diagnostic use only.
- Human materials used in kit components were tested and found to be negative for HIV, Hepatitis B and Hepatitis C. However, for safety reasons, all kit components should be treated as potentially infectious.
- Kit reagents contain sodium azide or ProClin as bactericides. Sodium azide or ProClin are hazardous to health and the environment. Substrates for enzymatic colour reactions may also cause skin and/or respiratory irritation. Any contact with the substances must be avoided. Further safety information can be found in the safety data sheet, which is available from Immundiagnostik AG on request.
- The 10x Wash buffer concentrate (WASHBUF) contains surfactants which may cause severe eye irritation in case of eye contact.

  Warning: Causes serious eye irritation. **IF IN EYES:** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: get medical Advice/attention.
- The stop solution consists of diluted sulphuric acid, a strong acid. Although diluted, it still must be handled with care. It can cause burns and should be handled with gloves, eye protection, and appropriate protective clothing. Any spill should be wiped up immediately with copious quantities of water. Do not breath vapour and avoid inhalation.

13. TECHNICAL HINTS

- Do not interchange different lot numbers of any kit component within the same assay. Furthermore we recommend not to assemble wells of different microtiter plates for analysis, even if they are of the same batch as wells from already opened microtiter plates are exposed to different conditions as sealed ones.
- Control samples should be analysed with each run.
- Reagents should not be used beyond the expiration date stated on kit label.
- Substrate solution should remain colourless until use.
- To ensure accurate results, proper adhesion of plate sealers during incubation steps is necessary.
- Avoid foaming when mixing reagents.
- Do not mix plugs and caps from different reagents.
- The assay should always be performed according to the enclosed manual.

14. GENERAL NOTES ON THE TEST AND TEST PROCEDURE

- This assay was produced and distributed according to the IVD guidelines of 98/79/EC.
- The guidelines for medical laboratories should be followed.
- *IDK*® and *IDK Extract*® are trademarks of Immundiagnostik AG.
- Incubation time, incubation temperature and pipetting volumes of the components are defined by the producer. Any variation of the test procedure, which is not coordinated with the producer, may influence the results of the test. Immundiagnostik AG can therefore not be held responsible for any damage resulting from incorrect use.
- Warranty claims and complaints regarding deficiencies must be logged within 14 days after receipt of the product. The product should be send to Immundiagnostik AG along with a written complaint.

15. REFERENCES

General literature

1. D'Haens, G. et al. Fecal calprotectin is a surrogate marker for endoscopic lesions in inflammatory bowel disease. *Inflammatory bowel diseases* **18**, 2218–24 (2012).
2. Fagerberg, U. L., Lööf, L., Merzoug, R. D., Hansson, L.-O. & Finkel, Y. Fecal calprotectin levels in healthy children studied with an improved assay. *Journal of pediatric gastroenterology and nutrition* **37**, 468–72 (2003).
3. Fagerhol, M. K. Calprotectin, a faecal marker of organic gastrointestinal abnormality. *Lancet* **356**, 1783–4 (2000).
4. Hestvik, E. et al. Faecal calprotectin concentrations in apparently healthy children aged 0-12 years in urban Kampala, Uganda: a community-based survey. *BMC pediatrics* **11**, 9 (2011).
5. Konikoff, M. R. & Denson, L. A. Role of fecal calprotectin as a biomarker of intestinal inflammation in inflammatory bowel disease. *Inflammatory bowel diseases* **12**, 524–34 (2006).
6. Poullis, A., Foster, R., Northfield, T. C. & Mendall, M. A. Review article: faecal markers in the assessment of activity in inflammatory bowel disease. *Alimentary pharmacology & therapeutics* **16**, 675–81 (2002).
7. Tibble, J. et al. A simple method for assessing intestinal inflammation in Crohn's disease. *Gut* **47**, 506–13 (2000).
8. Tibble, J. A., Sigthorsson, G., Bridger, S., Fagerhol, M. K. & Bjarnason, I. Surrogate markers of intestinal inflammation are predictive of relapse in patients with inflammatory bowel disease. *Gastroenterology* **119**, 15–22 (2000).
9. Tøn, H. et al. Improved assay for fecal calprotectin. *Clinica chimica acta; international journal of clinical chemistry* **292**, 41–54 (2000).
10. van Rheenen, P. F., Van de Vijver, E. & Fidler, V. Faecal calprotectin for screening of patients with suspected inflammatory bowel disease: diagnostic meta-analysis. *BMJ (Clinical research ed.)* **341**, c3369 (2010).

Literature using IDK® Calprotectin ELISA [K 6927]

11. Chen, C.-C., Huang, J.-L., Chang, C.-J. & Kong, M.-S. Fecal calprotectin as a correlative marker in clinical severity of infectious diarrhea and usefulness in evaluating bacterial or viral pathogens in children. *Journal of pediatric gastroenterology and nutrition* **55**, 541–7 (2012).

12. Langhorst, J. et al. Non-invasive Marker der Entzündungsaktivität bei Patienten mit chronisch entzündlichen Darmerkrankungen (CED): Vergleich von Lactoferrin, Calprotectin, PMN-Elastase im Stuhl, Serum-CRP und klinischen Aktivitätsindizes. *Zeitschrift für Gastroenterologie* **45**, P261 (2007).

13. Schröder, O., Naumann, M., Shastri, Y., Povse, N. & Stein, J. Prospective evaluation of faecal neutrophil-derived proteins in identifying intestinal inflammation: combination of parameters does not improve diagnostic accuracy of calprotectin. *Alimentary pharmacology & therapeutics* **26**, 1035–42 (2007).

Used symbols:


Temperature limitation

Catalogue number

In Vitro Diagnostic Medical Device

To be used with


Manufacturer

Contains sufficient for <n> tests

Lot number


Use by


Attention


Consult instructions for use

Consult specification data sheet


Irritant